In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 19-1473V

BRANDY SAWYER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: June 12, 2023 Special Processing Unit (SPU); Ruling on the Record; Ruling on Entitlement; Table Injury; Findings of Fact; Statutory Six Month Requirement; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Lauren Kells, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On September 25, 2019, Brandy Sawyer[2] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[3] (the "Vaccine Act"). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine received on

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] At the time of filing, Petitioner's last name was Phipps, but the caption was amended after her name changed (ECF Nos. 18,19).

[3] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

October 3, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

The parties dispute whether Petitioner can meet the "severity requirement" applicable to all Program claims. For the reasons discussed below, I find that the sequela of Petitioner's SIRVA continued for at least six months, and that Petitioner is otherwise entitled to compensation.

I. Relevant Procedural History

The case was activated on October 7, 2019 (ECF No. 9). On February 25, 2021, Respondent filed his Rule 4(c) Report (ECF No. 22). Respondent agreed that Petitioner could satisfy the criteria set forth in the Vaccine Injury Table and the Qualifications and Aids to Interpretation for SIRVA. However, Respondent maintained that the medical records did not demonstrate that Petitioner experienced the residual effects of her SIRVA for more than six months, and thus she did not meet the statutory severity requirement.

Petitioner filed additional evidence on July 29, 2021 (ECF No. 26). On September 16, 2021, a telephonic status conference was held, and the parties agreed that the issue should be briefed (ECF No. 28).

On January 17, 2022, Petitioner filed a motion for a ruling on the record (ECF No. 32). On March 18, 2022, Respondent filed a response (ECF No. 34). The issue of Petitioner's entitlement to compensation is now ripe for resolution.

II. Factual Findings and Ruling on Entitlement

A. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding the claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). "Medical records, in general, warrant consideration

as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The Federal Circuit has "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes).

In order to state a claim under the Vaccine Act, a petitioner must demonstrate that they:

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

Section 11(c)(1)(D).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[4] a petitioner must establish that he or she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a).

[4] In summary, a petitioner must establish receipt of a vaccine covered by the Program, administered either in the United States and its territories, or in another geographical area but qualifying for a limited exception; that residual effects of the injury continued for more than six months (or meet the severity requirement in other ways not applicable in this case); and no civil suit has been filed and no award or settlement has been collected for the injury. *See* Section 11(c)(1)(A)(B)(D)(E).

Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation ("QAI") are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

B. Relevant Factual History

The only factual issue disputed by the parties is whether the residual effects of Petitioner's shoulder injury continued for at least six months. Below I provide only a brief overview of facts pertinent to this specific issue.

1. Medical Records

On October 3, 2017, Petitioner received a flu vaccine intramuscularly in her right deltoid at Warrensville Drug Store in Warrensville, North Carolina. Ex. 6 at 3. Seventeen

days later, on October 20th, she was seen by her primary care provider ("PCP") Dr. Gregory Hershner, reporting right arm pain. Ex. 2 at 23. She reported that she had gotten a flu shot on October 3 and had pain and burning in her arm since then. *Id*. She was diagnosed with tendonitis of her right shoulder and given prednisone. *Id*. at 24.

Petitioner returned to Dr. Hershner on December 4, 2017, reporting ongoing right shoulder pain. Ex. 2 at 15. She experienced some improvement with oral prednisone, but reported that the pain started again six days earlier with a sudden movement to catch falling dishes. *Id*. at 15-16. The pain was worse when reaching backward or lying on her left side with her right arm hanging down. *Id*. Dr. Hershner administered a steroid injection and referred Petitioner for chiropractic therapy. *Id*. at 16.

Petitioner was seen by Cameron Current, D.C. for right shoulder pain on December 6, 14, and 20, 2017. Ex. 3 at 4-6. She was diagnosed with deltoid tendinitis, and chiropractic manipulation, traction, electrical stimulation and ultrasound were applied. *Id*.

Petitioner reported to orthopedist Dr. Ronald Benfield on January 26, 2018. Ex. 4 at 8, 10. She reported right shoulder pain that began after a flu injection. *Id*. at 9. Dr. Benfield assessed her with pain of the right shoulder joint, and administered a steroid injection. *Id*.

On February 9, 2018, Petitioner followed up with Dr. Benfield. Ex. 4 at 5, 7. She reported that her right shoulder was "markedly better as a consequence of the injection we gave her on her last visit." *Id*. at 7. She now reported full range of motion of her shoulder with no pain. *Id*. Because she was doing well, Dr. Benfield directed her to return only as needed. *Id*.

Petitioner was seen by Dr. Hershner on March 16, 2018. Ex. 2 at 10. The record indicates that the reason for the visit was hypertension and allergies. *Id*. The visit diagnoses included right shoulder tendonitis and "[o]ther shoulder lesions, right shoulder," but there is no other mention of her shoulder. *Id*. at 10-14. There is no evidence of Petitioner seeking treatment for her shoulder in the next two and one-half months, and this timeframe includes the six-month anniversary of her onset.

On June 1, 2018, Petitioner returned to her PCP Dr. Hershner, now reporting a return of her right shoulder pain. Ex. 2 at 3. She reported that the pain was in the anterior margin of the deltoid muscle, and was "very similar to the episode she had in October and December last year." *Id*. She also reported that this episode "started a couple of weeks ago after she had very vigorously been cleaning mirrors and windows in her

house." *Id*. at 3-4. On examination, she was tender to palpation at the anterior deltoid margin. *Id*. at 4. She had no other tenderness, and normal range of motion and strength. *Id*. Dr. Hershner noted that Petitioner had "a very high deductible with her health insurance. With this in mind, will use another steroid injection." *Id*. He administered a steroid injection, and did not recommend imaging or an orthopedic or physical therapy referral. *Id*.

No further medical records have been filed.

2. Affidavits

Petitioner submitted two affidavits in support of her claim. Exs. 5 and 7. In her supplemental affidavit, she averred that during the February to June 2018 timeframe, she needed help to dress and undress her upper body to limited range of motion in her right arm. Ex. 7 at ¶ 4. She had difficulty with everyday cleaning tasks and sleep interrupted by shooting pains in her right shoulder. *Id*. During this time, she took Aleve and used a TENS[5] unit at home to treat her pain. *Id*. She explained that she ordered a TENS unit, which her chiropractor had used, from Amazon in December 2017, as it was cheaper and easier to do this at home. *Id*. at ¶ 5. She filed an Amazon invoice for a December 23, 2017 order billed to Petitioner that included a TENS unit. Ex. 8.

C. The Parties' Arguments

Petitioner asserts that following the January 2018 steroid injection, her shoulder pain had not fully resolved, but she did not seek care for her right shoulder in part due to her high insurance deductible. Petitioner's Motion for a Ruling on the Record ("Mot.") at 7. When she did return to Dr. Hershner in June 2018, she asserts that she reported a "**return** of right shoulder pain, **similar to the pain she had in October and December of last year**." Mot. at 7 (emphasis in original).

Petitioner further explains why she was not more actively seeking treatment: the steroid injection she received in late January 2018 provided pain relief, because "[s]teroid injections are known to provide a decrease of pain when injected into the shoulder joint." Mot. at 7. In support of her argument, Petitioner cites a review article titled "Treatment

[5] TENS is an abbreviation for transcutaneous electrical nerve stimulation, which involves electrical stimulation of nerves that interferes with transmission of pain signals. *TENS* and *transcutaneous electrical nerve stimulation*, DORLAND'S ONLINE, https://www.dorlandsonline.com/dorland/definition?id=108464 (last visited June 12, 2023).

Strategy for Frozen Shoulder,"[6] which states that "ultrasonography-guided intra-articular and rotator interval steroid injections in 122 patients with [frozen shoulder] resulted in a notable decrease in pain at 6 weeks. The result was maintained at 12 weeks, but not at 26 weeks." Ex. 9 at 3.

Respondent maintains that the evidence demonstrates that Petitioner's condition lasted for only four months, precluding recovery under the Vaccine Act. Respondent's Response to Petitioner's Motion for a Fact Ruling ("Resp.") at 2. By February 9, 2018, Petitioner had full range of motion and no pain. *Id*. at 6. Respondent acknowledges that Petitioner's March 16, 2018 treatment record included a diagnosis of right shoulder tendonitis, but asserts that because this record is otherwise silent on Petitioner's right shoulder pain, it is "unlikely that right shoulder pain was mentioned or discussed at this visit." *Id*. at 4 n.2.

Respondent also asserts when Petitioner returned to Dr. Hershner for right shoulder pain in June 2018, that pain was precipitated by "very vigorously" cleaning mirrors and windows in her home, and she had normal range of motion, which is inconsistent with SIRVA. Resp. at 7. Respondent characterizes this as a "different injury" that occurred later, and does not satisfy the severity requirement. *Id*. Respondent cites *Cetlin-Salter v. Sec'y of Health & Human Servs.*, No. 16-792V, 2019 WL 1270432 (Fed. Cl. Spec. Mstr. Feb. 21, 2019), in which the petitioner sought care until four months after vaccination, at which point she was doing well. Thereafter, the *Cetlin-Salter* petitioner did not seek care for her shoulder again for another *year*.

Respondent otherwise finds Petitioner's affidavit evidence to be limited and unpersuasive, asserting that she did not discuss the steroid injection or any waxing and waning of symptoms following the injection, and did not provide corroborating witness affidavits. *Id*.

D. Statutory Severity Requirement

In this case, there is no dispute about whether Petitioner suffered a vaccine-related injury in the first place. The parties dispute only whether the injury meets the statutory severity requirement, which requires that a Petitioner demonstrate residual effects of a vaccine injury that continue for more than six months.

The record supports the conclusion that Petitioner's injury was treated conservatively with oral steroids, chiropractic care, steroid injections, and a TENS unit.

[6] Cho. Et. al., *Treatment Strategy for Frozen Shoulder*, Clinics in Orthopedic Surgery 2019; 11:249-257.

Following the January 2018 steroid injection, Petitioner experienced a period of relief from her symptoms, and during this time her symptoms abated to a point that formal treatment was not required. However, her shoulder pain returned approximately four months later. While she related the return of her shoulder pain to vigorous cleaning, she also described her pain as a "return" of shoulder pain, and described it as being similar to her prior shoulder pain. It is thus less likely that Petitioner's shoulder symptoms for which she sought care in June 2018 were a new injury, but rather a *return* of her SIRVA-related pain spurred by the cortisone injection wearing off and cleaning, which is a normal daily activity.

This case is not comparable to *Cetlin-Salter*. There, the petitioner's injury also appeared to have resolved within four months – but that claimant did not seek care again until *a year later* after a weight-lifting injury. In this case, by contrast, the lull in treatment can be attributed to a steroid injection, the beneficial effects of which wore off not too long after. The gap in time is thus not comparable, and less supportive of the conclusion that an intervening occurrence explained the return of pain.

The facts of this case are in fact more analogous to *Cross v. Sec'y of Health & Human Servs.*, No. 19-1958V (Fed. Cl. Spec. Mstr. Jan. 6, 2023). The *Cross* petitioner treated for less than a month and a half, receiving a steroid injection forty days after vaccination. Thereafter, the petitioner did not seek care for her shoulder pain again until six months later. I nevertheless found that the "six-month gap in Petitioner's treatment for her shoulder is at least partially explained by the fact that she received a cortisone injection on October 22, 2018, for her shoulder pain, which subsequently provided significant relief for a period of time." *Id*. at *5. Here too, Ms. Sawyer received significant pain relief from the January 2018 steroid injection, resulting in her not seeking care for several months.

The gap in formal treatment speaks not to the existence of Petitioner's injury, but to its intensity, and thus is relevant to damages. Petitioner experienced a relatively mild SIRVA, and obtained good relief from treatment, which would suggest a relatively modest damage award is appropriate. But it does not defeat the claim entirely.

E. Finding Regarding QAI Criteria for Table SIRVA

Respondent agrees that Petitioner has met the SIRVA QAI requirements.

1. Other SIRVA QAI Criteria

With respect to the remaining SIRVA QAI criteria, which are uncontested, the record contains sufficient evidence showing they are satisfied in this case. *See* 42 C.F.R.

§ 100.3(c)(10)(i) & (iii)-(iv). A thorough review of the record in this case does not reveal either a prior or other condition or abnormality that would explain Petitioner's symptoms, or pain or limited ROM other than in her left shoulder. Exs. 3, 7, 8, 14. Thus, all elements of a Table SIRVA claim have been preponderantly established.

E. Other Requirements for Entitlement

Because Petitioner has satisfied the requirements of a Table SIRVA, she need not prove causation. Section 11(c)(1)(C). However, she must satisfy the other requirements of Section 11(c) regarding the vaccination received, the duration and severity of the injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence which fulfills these additional requirements. Exs. 1, 5.

Conclusion

Based on my review of the record as a whole, I find that it is more likely than not that Petitioner experienced the residual effects of her injury for at least six months. I also find that all SIRVA Table requirements are met, as are other requirements for entitlement. Therefore, Petitioner's motion for a ruling on the record that she is entitled to compensation is **GRANTED**.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master